

Docket No. 041497-015

Claims

1. A process for the determination of *H. pylori* in a fecal specimen which comprises:

(a) dispersing a fecal specimen in a sample diluent;

5 (b) contacting the fecal specimen in the diluent with a first antibody to form a complex of the antibody and the antigen;

(c) separating said specimen and said complex;

10 (d) exposing the complex to a second antibody and a portion of the second antibody reacting with said complex, one of said first and second antibody being selected from the group consisting of polyclonal antibodies for *H. pylori* antigen, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof, and the other being a *Helicobacter* or *Camplobacter* genus specific monoclonal antibody, one of said

15 first and second antibody being bound to a solid carrier and the other being labeled with a detection agent; and

(e) detecting the amount of the labeled antibody and in turn determining the presence of *H. pylori* antigen in said fecal specimen.

2. The process of claim 1 wherein the first antibody is bound to a solid carrier and the second antibody is labeled with a detection agent.

3. The process of claim 1 wherein the first antibody is labeled with a detection agent and the second is bound to a solid carrier.

4. The process of claim 1 wherein the sample diluent is a protein based diluent.

5. The process of claim 1 wherein said first antibody is said genus specific monoclonal antibody and said second antibody is

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selected from the group consisting of polyclonal antibodies, a plurality of monoclonal antibodies and mixtures thereof.

6. The process of claim 4 wherein the sample diluent contains a protein selected from the group consisting of fetal bovine serum, normal goat serum, guinea pig serum, horse serum, casein, albumin, gelatin, and bovine serum albumin.

7. The process of claim 1 wherein after exposing the complex to the second antibody, the complex is washed with a buffer that reduces cross-reactivity or otherwise improves the specificity of the assay.

8. The process of claim 5 wherein the second antibody is a polyclonal antibody obtained by sensitizing an antibody-producing mammal with *H. pylori* cells.

9. The process of claim 3 wherein said detection agent is selected from the group consisting of alkaline phosphatase and beta galactosidase horseradish peroxidase.

10. The process of claim 7 wherein said wash is phosphate buffered saline.

11. A process for the determination of *H. pylori* in a fecal specimen which comprises:

(a) dispersing a fecal specimen in a diluent;

(b) contacting the fecal specimen in the diluent with a

5 first antibody reactive with *H. pylori* antigen bound to a solid carrier and a second labeled antibody reactive with *H. pylori* to form a complex of the antibodies and the antigen, one of said first and second antibody being selected from the group consisting of polyclonal antibodies, a plurality of *H. pylori*

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10 antigen specific monoclonal antibodies and mixtures thereof and the other being a Helicobacter or Camplobacter genus specific monoclonal antibody;

(c) separating said specimen and said complex;

15 (d) detecting the labeled antibody and in turn determining the presence of *H. pylori* antigen in said fecal specimen.

12. A process for the determination of *H. pylori* in a fecal specimen which comprises:

(a) dispersing a fecal specimen in a sample diluent; (b) contacting the fecal specimen in the diluent with a Helicobacter or Camplobacter genus specific monoclonal antibody bound to a solid carrier to form a complex of the antibody and the antigen;

(c) separating said specimen and said complex;

(d) contacting the antibody-antigen complex formed in step (b) with a primary antibody for *H. pylori* antigen obtained from an antibody-producing species to produce an antibody-antigen-antibody complex;

10 (e) removing the primary antibody not present in the complex from step (c);

15 (f) contacting the antibody-antigen-antibody complex formed in step (e) with a secondary antibody, said secondary antibody being an antibody for the antibody-producing species, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and

20 (g) determining the presence of *H. pylori* antigen in said fecal specimen.

13. A kit for the determination of *H. pylori* in a fecal specimen including a plate of wells having bound thereto a genus specific monoclonal antibody for *H. pylori* antigen, a protein-based sample diluent and a plurality of labeled antibodies for *H. pylori* antigen.